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### Wearable device and method for delivering intravenous solution

Verkerke, Gijsbertus Jacob; Heintzen, Maximilian Justus; Weijermans, Niels Arnold

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TITLE: Wearable device and method for delivering intravenous solution

## FIELD AND BACKGROUND OF THE INVENTION

The invention relates to a wearable device and a method for delivering an intravenous ("IV") solution from a flexible bag to tubing connected to an IV delivery implement, such as a needle or a catheter. Intravenous  
5 administration of a solution from an IV bag typically uses pressure resulting from gravity. To maintain pressure resulting from gravity, the IV bag is suspended at a level higher than the level range of the patient body, for instance from a pole projecting from a foot or mounted to a bed. Such a pole severely restricts the freedom of movement of the patient. IV administration of  
10 medication may be required for prolonged periods of time. Restricting mobility of a patient for a prolonged period of time is inconvenient for the patient, increases the need of nursery care and is particularly disadvantageous since it has been found that physical exercise and mobility has a positive effect on patient health, so that restricting patient mobility has an adverse effect on  
15 patient health and tends to lead to longer stays in hospital.

Delivery of an IV solution may be supported by a peristaltic or piston driven IV pump. Use of such pumps is generally indicated if a specific amount of a pharmacologic agent is to be administered and/or fluid overload is to be prevented. However, such pumps are not suitable to be worn on the patient  
20 body due to weight, size and certified use restrictions and usually mounted to an IV pole, so that no improvement regarding patient mobility is achieved. Furthermore, such IV pumps are costly.

International patent application WO 98/38953 discloses an infusion delivery device comprising a holder with, in the holder, a bag holding chamber  
25 for holding an IV bag for feeding an intravenous solution. The IV bag has first and second opposite flexible walls and a port adapted for discharging the solution along a flow path into tubing for delivery to a patient. The IV bag holding chamber has opposite largest sides dimensioned for allowing the IV

bag to be accommodated in the bag holding chamber with one of the first and second opposite flexible walls arranged flat against a wall surface of one of the largest sides and at least one opening for allowing ventilated communication with ambient pressure of an environment of the holder. Also arranged in the holder is a pressing member bounding a pressure chamber hermetically closed for allowing generation of a pressure in the pressure chamber which is higher than the ambient pressure. The pressing member has a pressure chamber wall extending along a substantial portion of the largest sides of the bag holding chamber. A pressurizer for generating a pressure in the pressure chamber higher than the ambient pressure is also provided in the holder.

The pressure chamber wall in the form of a bellows is arranged for, in response to an increasing pressure in the pressure chamber, displacing towards one of the largest sides of the bag holding chamber on a side of the bag opposite of a side of the bag where the pressing member is located. Thus, IV is pressed out of the IV bag as air is pumped into the pressure chamber.

## SUMMARY OF THE INVENTION

It is an object of the invention to provide a device for delivering IV solution from a flexible IV bag that is wearable on a patient body and reliably delivers substantially the entire contents from an IV bag regardless orientation of the device and accelerations to which the device is subjected as it is worn on the patient body, while allowing the device to be of a more compact size.

According to the invention, this object is achieved by providing a device according to claim 1. The invention can also be embodied in a method according to claim 15.

Substantially all of the solution in the IV bag is reliably pressed out of the IV bag without leaving back a pocket in which solution is trapped in by contact area portions where the walls of the IV bag are pressed against each

other. Because the pressure chamber wall is flexible and arranged for contacting the first or second wall of the IV bag and, as pressure in the pressure chamber is increased, while solution is delivered from the IV bag, causes the first and second wall of the IV bag to contact each other, first in an  
5 initial contact area remote from the port and subsequently causing the contact area to grow towards the port, the solution in the IV bag is reliably urged towards the port in the direction of growth of the contact area.

Because of the flexibility of the flexible pressing member wall, the pressing member shape can accommodate to the shape of a full bag in the IV  
10 bag holding chamber. Thus, the pressing member can temporarily be compressed to a very small volume, which allows the device to be of a compact size. Because the pressing member wall is flexible, it can bulge out as the volume of the pressure chamber increases, allowing the contact area to grow from the initial contact area towards the outlet port, which ensures driving out  
15 of virtually all of the IV solution without leaving pockets of IV solution in the IV bag. Because no separate mechanism is needed for this purpose space, costs and weight are saved.

Particular elaborations and embodiments of the invention are set forth in the dependent claims.

20 Further features, effects and details of the invention appear from the detailed description and the drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

25 Figs. 1-3 are schematic side views in cross-section of a first example of a device according to the invention in three successive stages of operation;

Fig. 4 is a schematic exploded view of the device shown in Figs. 1-3;

Fig. 5 is a perspective view of a pressing member of a device according to a second example according to the invention;

Fig. 6 is a perspective view of a strip of wall material folded in a configuration for manufacturing a pressing member of a device according to a third example according to the invention; and

Fig. 7 is a perspective view of the pressing member of Fig. 7 in  
5 completed form.

## DETAILED DESCRIPTION

The invention is first described with reference to the example shown in  
10 Figs. 1-4. In these figures, a wearable infusion delivery device 1 with a holder 2 is shown.

In the holder 2, an IV bag holding chamber 3 for holding an IV bag 4 for feeding an intravenous (IV) solution is located. Such an IV bag 4 has first and second opposite flexible walls 5, 6 and a port 7 adapted for discharging the  
15 solution along a flow path 7 into tubing connected to the port 7 for delivery to a patient. Generally, such an IV bag has a height of 20 - 26 cm, a width of 13.5 - 16 cm and a thickness when full of 4 - 6 cm and may contain for instance 250-500 ml of IV solution. The IV bag holding chamber 3 has opposite largest sides 8, 9 which are dimensioned so that the IV bag 4 can be accommodated in  
20 the IV bag holding chamber 3 with one of the first and second opposite flexible walls 5, 6 arranged flat against a wall surface 10 of one of the two largest sides 8 of the IV bag holding chamber 3. A passage 11 for the port 7 is dimensioned such that an opening is left between the passage 11 and the port 7 allowing ventilated communication with ambient pressure of an environment of the  
25 holder 1. Openings may also be provided elsewhere, for instance between housing parts 12 and 13 or where a window 14 is mounted to housing part 12.

Also in the holding chamber 3, a pressing member 15 bounding a pressure chamber 16 is provided. The pressure chamber 16 is hermetically closed for allowing generation of a pressure in the pressure chamber 16, which  
30 is higher than the ambient pressure. The pressing member 15 has a flexible

pressure chamber wall 17 bounding the pressure chamber 16 and extending along a substantial portion of the largest sides 8, 9 of the IV bag holding chamber 3 so that, in use, the flexible pressure chamber wall 17 contacts substantially the entire surface area of the first or second wall 5, 6 of the IV solution bag 4. Small edge areas of the contacted bag wall 5 or 6 of up to 5 or 10% of the distance to the opposite edge of the respective bag wall 5, 6 may be left free without significantly reducing the effectiveness of the device. In Figs. 1-3, the pressing member 15' in uncompressed condition and with ambient pressure in the pressure chamber 16 is shown in dash-and-dot lines.

For generating a pressure in the pressure chamber 16 higher than the ambient pressure, a pressurizer in the form of a pump 18 is provided, which communicates with the pressure chamber 16 via a pressure chamber port 19.

In Fig. 1, the IV bag 4 is pre-filled with a volume of solution. A valve (not shown) in the port 19 is open so that the pressing member 15 can be compressed to some extent from an unloaded and unpressurized condition 15' as shown in dash and dot lines. Thus, when a full IV bag 4 is placed in the holder 1, the pressing member 15 can be compressed easily and occupies very little space. Accordingly, the full IV bag 4 can be accommodated in a relatively flat and accordingly compact housing 2. The valve at the port 19 to the pressing member 15 may be a ventilating valve opening communicating with the environment via a channel other than the channel leading to the pump 18, or, if the pump allows fluid to flow back when not driven, a valve that can be brought in a one way operating condition for allowing flow into the pressure chamber 16 only and into an operating condition in which the valve is open in two opposite directions for allowing outflow through the pump 18.

For delivering solution from the IV bag 4, the valve at the port 19 to the pressing member 15 is closed for preventing fluid flow out of the pressure chamber 16 and the pump 18 is activated for driving a pressure medium into the pressure chamber 16. As is best seen in Figs. 2, in response to an increasing pressure in the pressure chamber 16, the flexible pressure chamber



wall 17 displaces towards the one of the two largest sides 8 of the IV bag holding chamber 3 on a side of the IV bag 4 opposite to the side of the IV bag 4 where the pressing member 15 is located.

This displacement of the flexible pressure chamber wall 17 causes IV solution to be pressed out of the IV bag 4 and, accordingly, to be delivered from the IV bag 4. The exerted pressure is preferably in a range that simulates pressure in gravity driven IV delivery. As IV solution is delivered from the IV bag 4, the volume of IV solution in the IV bag 4 decreases and the wall 6 of the IV bag 4 in contact with the flexible pressure chamber wall 17 is pressed towards the opposite wall 5 of the IV bag 4. After an amount of IV solution has been pressed out of the IV bag 4, the wall 6 of the IV bag 4 in contact with the flexible pressure chamber wall 17 is pressed into contact with the opposite wall 5 of the IV bag 4. This opposite wall 5 of the IV bag 4 rests against the largest side 8 of the IV bag holding chamber 3 on a side of the IV bag 4 opposite to the side of the IV bag 4 where the pressing member 15 is located. The first and second walls 5, 6 of the IV bag 4 contact each other, first in an initial contact area 20 remote from the port 7 and then the contact area grows towards the port 7 until a condition as shown in Fig. 3 is reached in which virtually all of the IV solution has been pressed out of the IV bag 4.

To ensure that liquid is reliably supplied from the IV bag until the bag is virtually empty, the contact area where the first and second walls 5, 6 of the IV bag 4 contact each other preferably grows towards the port 7 until the contact area extends over at least 70% and more preferably at least 75% or 80% of the size of the IV bag 4 from the port 7 to an end 21 of the first and second walls 5, 6 of the IV bag 4 most remote from the port 7.

Because the contact area grows from an initial contact area 20 remote from the port 7 towards the port 7, it is reliably ensured that substantially the entire volume of solution from an IV bag is delivered regardless of the orientation of the device and accelerations to which the device is subjected during wear. In particular, the formation of a pocket in which solution is

trapped in by contact area portions where the walls 5, 6 of the IV bag 4 are pressed against each other is avoided and the IV solution in the IV bag 4 is reliably urged towards the port 7 in the direction of growth of the contact area. Formation of pockets is not only disadvantageous because IV solution is left in the IV bag, but also because, on the one hand, energy is consumed for further increasing pressure since not an entire bag volume of IV solution has been delivered, while, on the other hand, no further IV solution is delivered since the remaining volume is trapped in a pocket.

Because of the flexibility of the flexible pressing member wall 17, the shape of the pressing member 15 adapts to the shape of a full IV bag 4 in the IV bag holding chamber 3. Thus, pressing member 15 can temporarily be compressed to a very small volume by allowing air to flow out. This allows the device 1 to be of a compact size. Because the flexible pressing member wall 17 ensures driving out of virtually all of the IV solution, no separate mechanism is needed for this purpose, which saves costs and weight.

The initial contact area 20 is located close to the end 21 of the first and second walls 5, 6 of the IV bag 4 most remote from the port 7. This is also close to an edge 22 of the pressing member 15 most remote from the port 7 and the passage 11. Thus, the contact area can grow over virtually the entire distance from the end 21 of the first and second walls 5, 6 of the IV bag 4 most remote from the port 7 to the port 7. Although it is particularly advantageous if the initial contact area 20 is located directly adjacent to the end 21 of the first and second walls 5, 6 of the IV bag 4 most remote from the port 7, a small distance to that end 21 is usually not problematic, in particular if, as in the present example, the initial contact area 20 does not extend to the edges 23, 24 of the IV bag 4 perpendicular to the edge 21 of the IV bag 4 most remote from the port 7, because IV solution between the initial contact area 20 and the edge 21 of the IV bag 4 most remote from the port 7 can flow away around the ends of the contact area as the contact area grows towards the edge 21 of the IV bag 4 most remote from the port 7. There will then also be a clearance between the

initial contact area 20 and edges 25, 26 of the pressing member 15 perpendicular to the edge 22 of the pressing member 15 most remote from the port 7 and the passage 11.

Because the initial contact area 20 is elongate in a direction transverse  
5 to a direction towards the port 7, it can grow predominantly towards the port 7, which is advantageous for reliable displacement of IV solution towards the port 7.

After an IV bag 4 has been emptied to such an extent or almost such an extent that no further solution is delivered, the housing 2 can be opened and  
10 the IV bag 4 can be removed and be replaced by a full one. Prior to closing the housing 2, the valve in the port 19 is opened to allow fluid used to pressurize the pressing member 15 to flow out of the pressing member 15, so that the pressing member can easily be compressed by the new, full IV bag 4.

In the present example, the location of the initial contact area 20 and  
15 the growth of the contact area towards the port 7 is achieved by providing that the flexible pressure chamber wall 17 is arranged such that displacement towards the opposite wall 8 of the IV bag holding chamber 3 causing the first and second walls 5, 6 of the IV bag 4 to contact each other requires deformation which is smaller at the initial contact area 20 than in areas closer  
20 to the port 7.

If pressure in the pressure chamber 16 is equal to ambient pressure, at the initial contact area 20 the flexible pressure chamber wall 17 is at a first distance from the opposite wall 8 of the IV bag holding chamber 3 while closely adjacent to the port 7 the flexible pressure chamber wall 17 is at a second  
25 distance from the opposite wall 8 of the IV bag holding chamber 3, which second distance is larger than the first distance. The distance of the flexible pressure chamber wall 17 to the opposite wall of the IV bag holding chamber 3 increases, preferably continuously, from the initial contact area 20 to the area closely adjacent to the port 7. Thus, when pressure in the pressure chamber is  
30 increased, causing the flexible pressure chamber wall 17 to bulge out, the walls

5, 6 of the IV bag 4 are pressed against each other and rest against the opposite wall 8 of the IV bag holding chamber 3 first in the initial contact area 20 remote from the port 7. As the flexible pressure chamber wall 17 bulges out further, the contact area grows towards the port 7.

5           In the present example, the gradual increase of the distance from the non-deformed pressing member 15 with ambient pressure in the pressure chamber 16 to the opposite wall 8 of the IV bag holding chamber 3 is obtained in a simple manner by providing that, in cross-sectional view along a plane perpendicular to the flexible pressure chamber wall 17 and oriented from the  
10           port 7 to the initial contact area 20, the pressure chamber 16 is elongate in a direction from the area closely adjacent to the port 7 to the initial contact area 20 and has a width which decreases from the initial contact area 20 to the area closely adjacent to the port 7. Such an essentially triangular cross-sectional shape of the pressure chamber 16 also allows the IV bag holding chamber 3 to  
15           be of an essentially rectangular cross section, seen in the same plane, so that the housing 2 can tightly fit around a full IV bag 4 pressing the pressing member 15 into a flat configuration in the IV bag holding chamber 3.

          For causing the opposite walls 5, 6 of the IV bag 4 to be initially pressed against each other and against the opposite wall 8 of the IV bag holding  
20           chamber 3 in an area 20 remote from the port 7, the difference between pressure exerted by the pressing member 15 in the initial contact area 20 and pressure exerted by the pressing member 15 closely adjacent to the port 7 should be larger than the difference in pressure in the IV bag 4 due to the difference in height between the area closely adjacent to the port 7 (usually at  
25           the top) and the initial contact area 20. To achieve this, the pressing member 15 is preferably of a material that is sufficiently stiff for causing a difference in retaining forces against bulging out to press the IV bag wall 5, 6 against the opposite wall 8 of the IV bag holding chamber 3, that is larger than the difference in liquid pressure in the IV bag due to the difference in height  
30           between the area closely adjacent to the port 7 (usually at the top) and the

initial contact area 20. To this end, the pressing member 15 may for instance be formed of resilient polymeric or elastomeric materials, such as PET, PVC or silicon rubber with a wall thickness of 0.1 – 0.5 mm for stiff materials (e.g. modulus of elasticity of 1.5-3 GPa), 0.5 - 3 mm for flexible and elastic materials (e.g. modulus of elasticity of 0.005 – 1 GPa) and 0.4 – 1 mm for intermediate materials (e.g. modulus of elasticity of 0.5 - 1 GPa).

For facilitating compressing the pressing member 15 to a flat shape, side walls 27 connected to the flexible pressure chamber wall are each provided with a fold 28 extending along a side of the flexible pressure chamber wall 17 for facilitating folding flat of the pressure chamber 15. Instead of a single fold 28, also a plurality of such folds may be provided.

If deformation of the flexible pressure chamber wall 17 causing the first and second walls 5, 6 of the IV bag 4 to be in contact with each other in areas 20 remote from peripheral edges of the first and second walls 5, 6, includes elastic stretching of the flexible pressure chamber wall 17, it is reliably ensured that the first and second walls 5, 6 of the IV bag 4 are initially pressed against each other only in the initial contact area 20 remote from the port 7.

In Fig. 5, an example of a different pressing member 65 is shown in which the sidewalls 77 are part of a rigid frame 79 to which the flexible pressure chamber wall 67 is attached along its periphery. When mounted in a housing of the delivery device, the rigid frame 67 is at a distance from an opposite wall of the IV bag holding chamber, which distance increases from the initial contact area towards the port. Thus, deformation of the flexible pressure chamber wall 67 required to press the IV bag walls against the opposite wall of the IV bag holding chamber is smaller at the initial contact area than at the port and increases towards the port, so that when the pressure in the pressing member 65 is increased, it reaches the opposite wall of the IV bag holding chamber initially at the initial contact area and then the contact area grows towards the port.

For efficient manufacturing, it is advantageous if the flexible pressure chamber wall 67 is arranged for deforming under influence of increasing pressure in the pressure chamber to a shape that is, at least initially, symmetrical about a first plane oriented perpendicular to a second plane in which the frame extends and transverse to a direction along the second plane towards the port. The flexible pressure chamber wall 67 may then for instance be of a substantially constant thickness.

However, for ensuring particularly effective displacement of solution from peripheral portions of the IV bag, it is advantageous if the flexible pressure chamber wall 67 is more elastic in zones 82 and 83 along at least sides of the frame 79 closest to and most remote from the port than in an area between these zones 82, 83. Also more elasticity in other zones 80, 81 along the frame 79 than in an area between the zones is advantageous for particularly effective displacement of solution from peripheral portions of the IV bag.

Pressurizing the pressing member 15, 65 may for instance be carried out by pumping a gas or ambient air into the pressing member 15, 65. However, it may also be provided that a liquid is pumped into the pressing member for driving solution out of the IV bag. Furthermore, for pressurizing the pressing member, also other solutions than a pump may be provided, such as a high pressure gas cartridge with a valve for allowing controlled flow from the cartridge into the pressing member or a bellows or cylinder having a stroke volume that is sufficient for displacing sufficient fluid into the pressing member for delivering all solution from an IV bag.

In Figs. 6 and 7, a pressing member 115 of a third example of a device according to the invention is shown in partially completed form and, respectively, in completed form. The pressing member 115 has a flexible pressure chamber wall 117 bounding the pressure chamber. If the pressing member is positioned in the IV bag holding chamber, the pressure chamber wall 117 extends along a substantial portion of the largest sides 8, 9 of the IV bag holding chamber 3. In use, the flexible pressure chamber wall 117 contacts

substantially the entire surface area of the first or second wall 5, 6 of the IV solution bag 4. Small edge areas of the contacted bag wall 5 or 6 of up to 5 or 10% of the distance to the opposite edge of the respective bag wall 5, 6 may be left free without significantly reducing the effectiveness of the device. At the top of the bag, an opening is provided to which a port can be mounted or connected.

In use, the pressing member 115 bulges out in essentially the same manner as the pressing member 15' shown in Figs. 1-3, except that the flexible pressure chamber wall 117 bulges out less and later along the side edges 131, 132. This results in the contact area growing from the initial contact area more centrally than in the example shown in Figs. 1-3, so that relatively large open areas are initially left along the side edges 131, 132 from and through which IV solution can easily and reliably be urged out of the IV bag.

The flexible pressure chamber wall 117 is quadrangular (preferably generally rectangular or trapezium shaped) and sealed to an opposite wall 129 along an edge 130 at a side most remote from the initial contact area (seam 139) and along mutually opposite side edges 131, 132 (seams 140 and 141). The flexible pressure chamber wall 117 and the opposite wall 129 are of generally identical dimensions and flexibility. A bottom panel 133 of the same or similar flexibility as the pressure chamber walls 117, 129 connects to the flexible pressure chamber wall 117 and the opposite wall 129 along bottom edges 134, 135 extending between ends 136, 137 of the side edges 131, 132 closest to the initial contact area. The bottom panel 133 extends from the flexible pressure chamber wall 117 to the opposite wall 129 and is provided with at least one fold 138 extending centrally between the bottom edges 134, 135 for facilitating folding flat of the pressure chamber 115.

The pressing member 115 of this third example of a device according to the invention can be manufactured from a strip of wall material by folding as shown in Fig. 6, sealing along the edge 130 at the side most remote from the initial contact area and along the mutually opposite side edges 131, 132. In the

shown pressing member 115, further seams 142, 143 have been made along folds extending along the bottom edges 134, 135 to ensure that the bottom panel 132 pleats inwardly when the pressing member 115 is empty and the pressing member 115 easily folds to a very flat configuration. For the same purpose, a seam may be provided along the fold 138 extending centrally  
5 between the bottom edges 134, 135.

Another advantage of a pressing member 115 of the device according to this example is that it is very flat when empty, because of the absence of side panels between the walls 117, 129, but nevertheless reliably causes the contact  
10 area to grow from the initial contact area towards the port 5 of the IV bag and outwardly to the side edges, thereby avoiding that IV solution remains trapped in pockets between the walls of the IV bag.

Several features have been described as part of the same or separate embodiments. However, it will be appreciated that the scope of the invention  
15 also includes embodiments having combinations of all or some of these features other than the specific combinations of features embodied in the examples.



## Claims

1. An infusion delivery device comprising:

a holder with, in the holder:

- a bag holding chamber for holding an IV bag for feeding an intravenous solution, the IV bag having first and second opposite flexible walls and a port adapted for discharging the solution along a flow path into tubing for delivery to a patient, wherein the IV bag holding chamber has opposite largest sides dimensioned for allowing the IV bag to be accommodated in said bag holding chamber with one of said first and second opposite flexible walls arranged flat against a wall surface of one of said largest sides and at least one opening for allowing ventilated communication with ambient pressure of an environment of the holder;
- a pressing member bounding a pressure chamber hermetically closed for allowing generation of a pressure in said pressure chamber which is higher than said ambient pressure, the pressing member comprising a pressure chamber wall extending along a substantial portion of the largest sides of said bag holding chamber; and

a pressurizer for generating a pressure in said pressure chamber higher than said ambient pressure;

wherein said pressure chamber wall is arranged for:

in response to an increasing pressure in said pressure chamber, displacing towards one of said largest sides of said bag holding chamber on a side of said bag opposite of a side of said bag where said pressing member is located;

characterized in that,

said infusion delivery device is wearable on a patient body;

said pressure chamber wall is flexible, arranged for contacting said first or second wall of said bag and for, while solution is delivered from said bag, causing said first and second walls of said bag to contact each other, first in an initial contact area remote from said port and subsequently causing said  
5 contact area to grow towards said port.

2. A device according to claim 1, wherein said initial contact area is located close to an end of said first and second walls of said IV bag most remote from said port.  
10

3. A device according to claim 1 or 2, wherein said initial contact area is elongate in a direction transverse to a direction towards said port.

4. A device according to any one of the preceding claims, wherein said  
15 flexible pressure chamber wall is arranged such that displacement towards the opposite wall of the IV bag holding chamber causing said first and second walls of said bag to contact each other requires deformation which is smaller at said initial contact area than in areas closer to said port.

20 5. A device according to any of the preceding claims, wherein, if pressure in said pressure chamber is equal to ambient pressure, at said initial contact area said flexible pressure chamber wall is at a first distance from said opposite wall of the IV bag holding chamber and closely adjacent to said port said flexible pressure chamber wall is at a second distance from said opposite  
25 wall, said second distance being larger than said first distance and said distance of said flexible pressure chamber wall to said opposite wall increasing from said initial contact area to said area closely adjacent to said port.

6. A device according to claim 5, wherein in cross-sectional view along a  
30 plane perpendicular to said flexible pressure chamber wall and oriented from

said port to said initial contact area, said pressure chamber is elongate in a direction from said area closely adjacent to said port to said initial contact area and has a width which decreases from said initial contact area to said area closely adjacent to said port.

5

7. A device according to claim 5 or 6, wherein, if pressure in said pressure chamber is equal to ambient pressure, in cross-sectional view along a plane perpendicular to said flexible pressure chamber wall and oriented from said port to said initial contact area, said pressure chamber is of triangular shape, a top of said triangular shape forming an end of said pressure chamber closely adjacent to said port.

10

8. A device according to any of the preceding claims, wherein said flexible pressure chamber wall is quadrangular and sealed to an opposite wall along an edge at a side most remote from said initial contact area and along mutually opposite side edges, wherein said flexible pressure chamber wall and said opposite wall are of generally identical dimensions and flexibility and wherein a bottom panel connects to said flexible pressure chamber wall and said opposite wall along bottom edges extending between ends of said side edges closest to said initial contact area and wherein said bottom panel extends from said flexible pressure chamber wall to said opposite wall and is provided with at least one fold extending centrally between said bottom edges for facilitating folding flat of said pressure chamber.

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9. A device according to any of the preceding claims, wherein deformation of said flexible pressure chamber wall causing said first and second walls of said bag to be in contact with each other in areas remote from peripheral edges of said first and second walls of said bag, includes elastic stretching of said flexible pressure chamber wall.

30

10. A device according to claim 9, further comprising a rigid frame to which said flexible pressure chamber wall is attached along its periphery, wherein said rigid frame is at a distance from an opposite wall of said bag holding chamber, said distance increasing from said initial contact area  
5 towards said port.

11. A device according to claim 10, wherein said flexible pressure chamber wall is arranged for deforming under influence of increasing pressure in said pressure chamber to a shape that is, at least initially, symmetrical  
10 about a first plane perpendicular to a second plane in which said frame extends and transverse to a direction along said second plane from said initial contact area towards said port.

12. A device according to any of the preceding claims, wherein said  
15 flexible pressure chamber wall is more elastic in zones along at least sides of said frame closest to and most remote from said port than in an area between said zones.

13. A device according to any of the claims 9-12, wherein said flexible  
20 pressure chamber wall is more elastic in zones along said frame than in an area between said zones.

14. A device according to any of the preceding claims, wherein the contact area where the first and second walls of the IV bag contact each other  
25 grows towards the port until the contact area extends over at least 70% and preferably at least 75% or 80% of a distance from the port to an end of the first and second walls of the IV bag most remote from the port.

15. A method of delivering intravenous solution from an IV bag having  
30 first and second opposite flexible walls and a port from which the solution is

delivered into tubing for delivery to a patient, using an infusion delivery device comprising a holder with, in the holder:

a bag holding chamber holding the IV bag, wherein the IV bag is accommodated in said bag holding chamber with one of said first and second  
5 opposite flexible walls arranged flat against a wall surface of one of said largest sides and the IV bag holding chamber is in open communication with ambient pressure of an environment of the holder;

a pressing member bounding a pressure chamber, the pressing member comprising a pressure chamber wall forming a boundary of said pressure  
10 chamber; and

a pressurizer generating a pressure in said pressure chamber which is higher than said ambient pressure;

wherein:

in response to an increasing pressure in said pressure chamber, said  
15 pressure chamber wall displaces towards one of said largest sides of said bag holding chamber on a side of said bag opposite to a side of said bag where said pressing member is located;

characterized in that,

said infusion delivery device is wearable on a patient body;

20 said pressure chamber wall is flexible and contacts substantially an entire surface area of said first or second wall of said bag; and

while solution is delivered from said bag, said first and second walls of said bag contact each other, first in an initial contact area remote from said port, said contact area subsequently growing towards said port.

Fig. 1

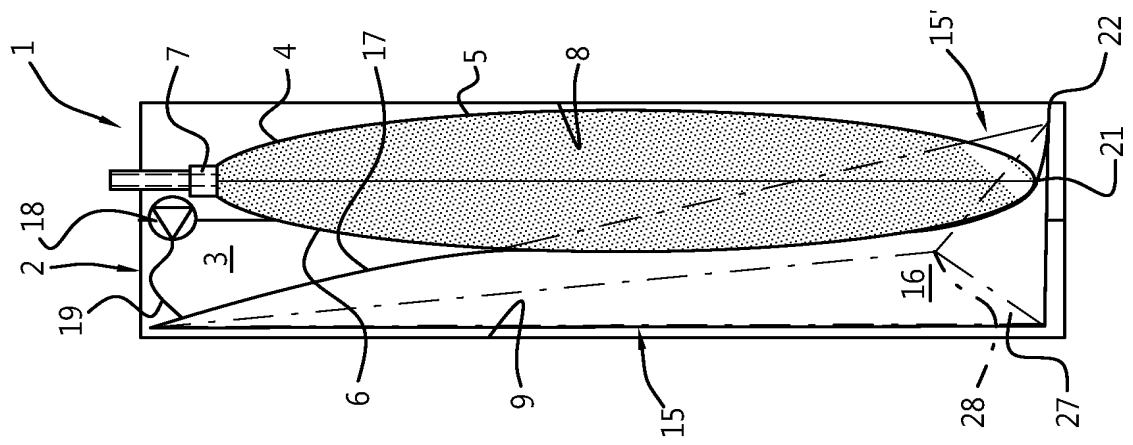


Fig. 2

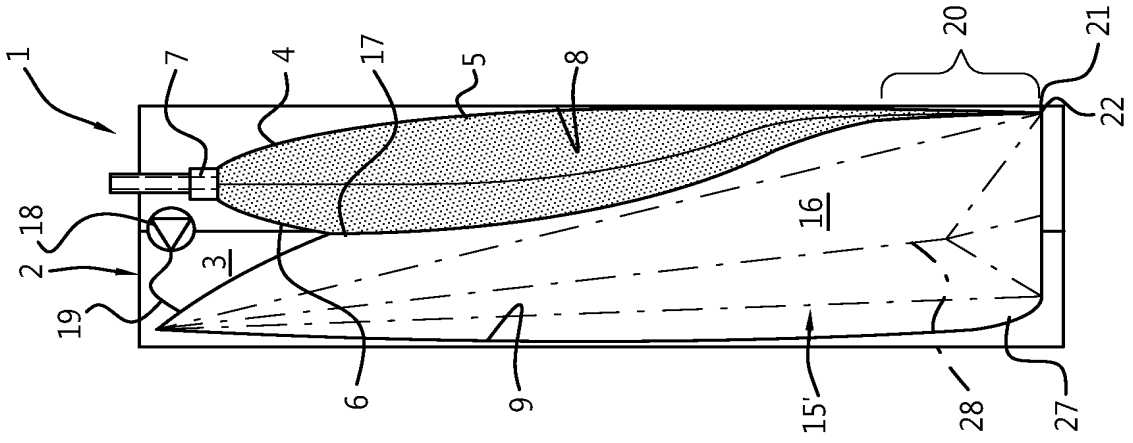
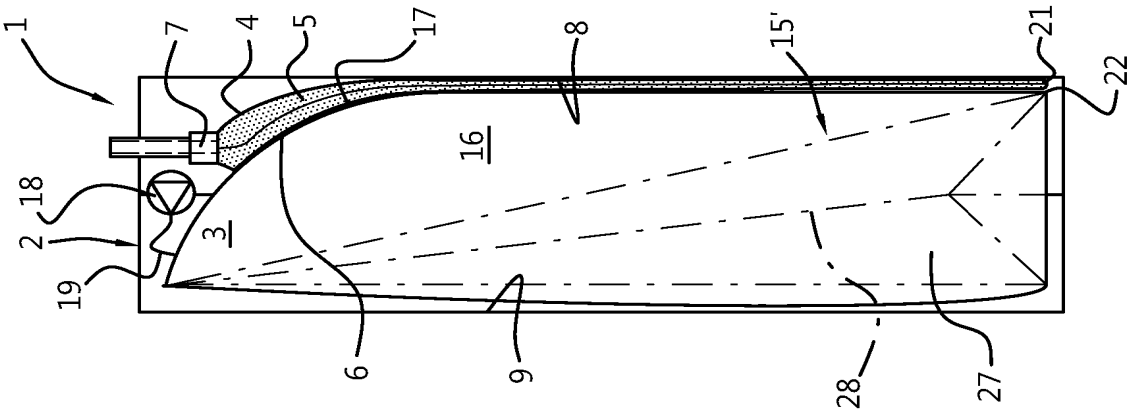


Fig. 3



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Fig. 4

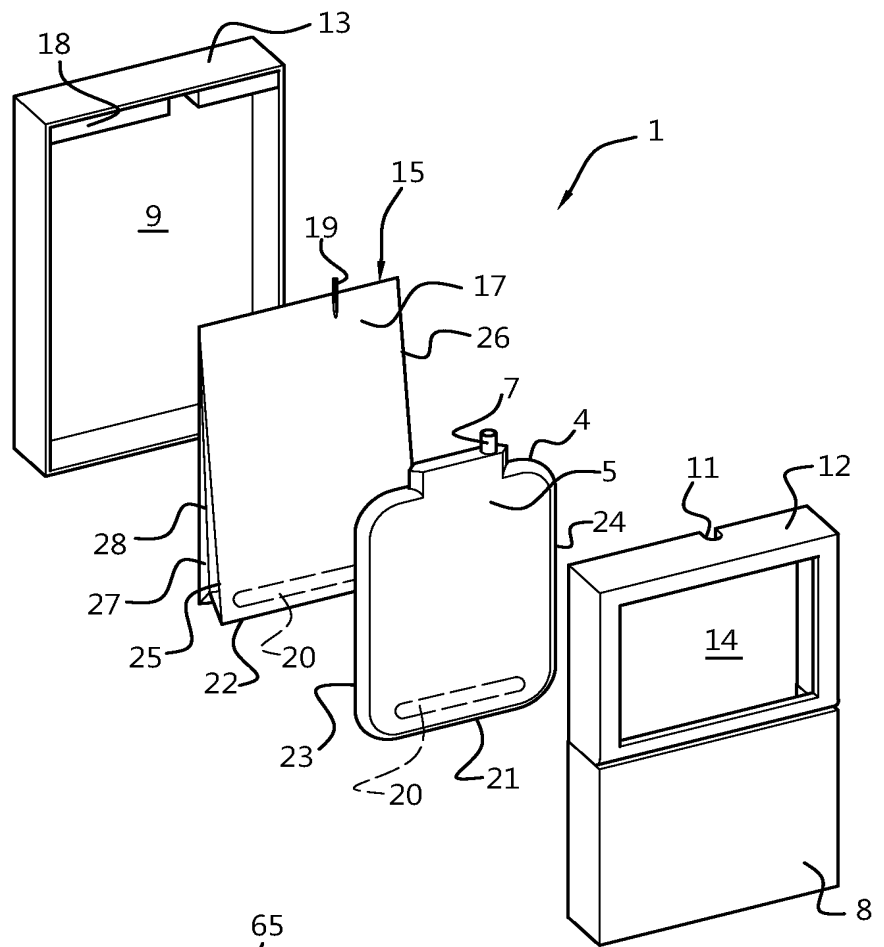
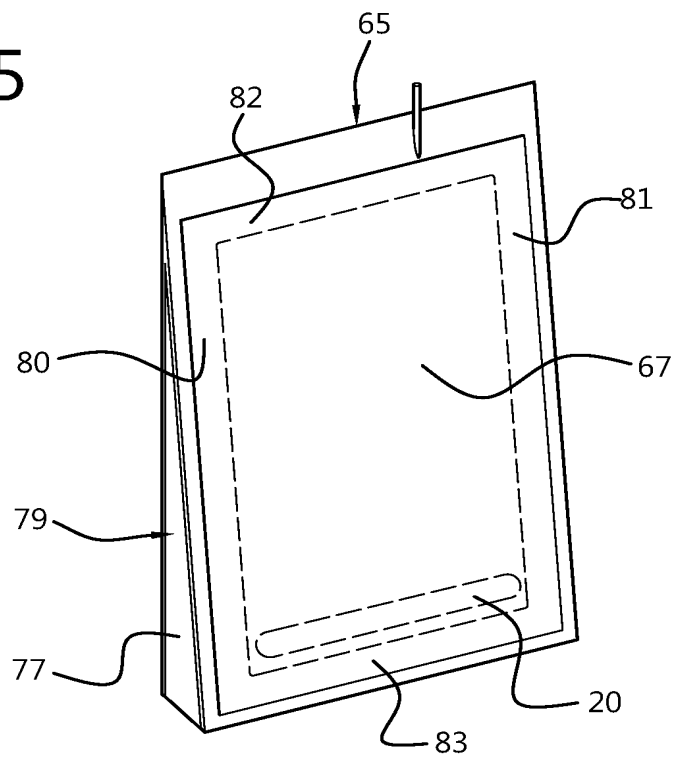


Fig. 5



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Fig. 6

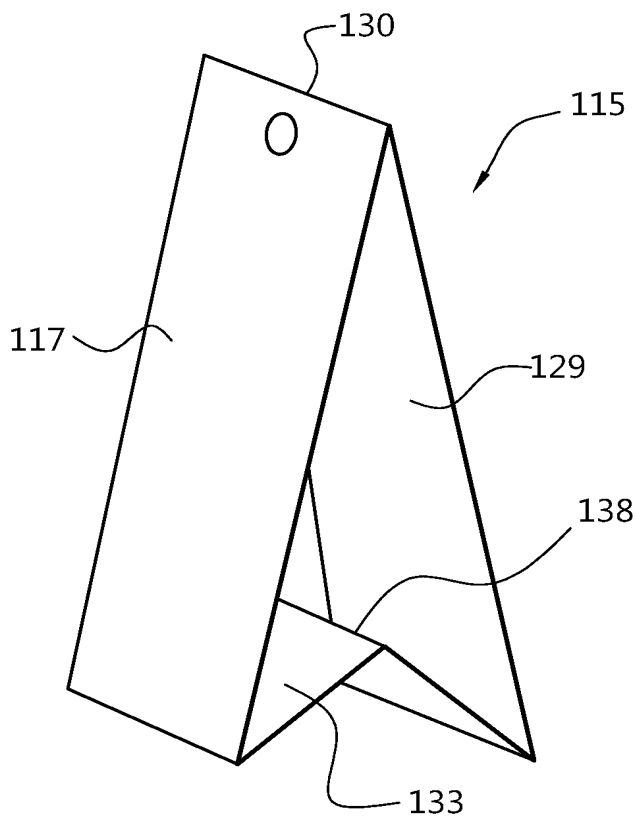
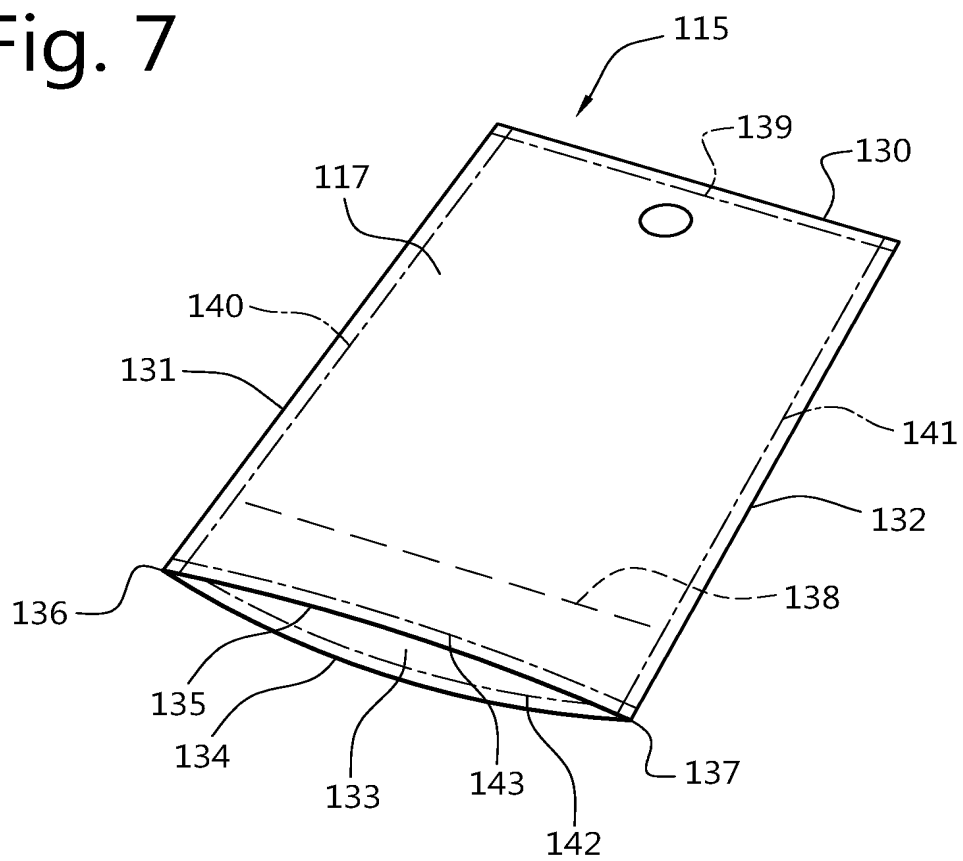


Fig. 7





# INTERNATIONAL SEARCH REPORT

International application No

PCT/NL2019/050429

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/148 A61M5/142  
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EP0-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98/38953 A1 (MEDICAL SOLUTIONS INC [US]; BLANKENSHIP CALVIN [US]; FARIES DURWARD I) 11 September 1998 (1998-09-11) page 2, paragraph 2; figures 1,2,4,5 -----	1-14
A	US 3 895 741 A (NUGENT BEDE STANISLAUS) 22 July 1975 (1975-07-22) figure 6 -----	1-14
A	US 5 656 033 A (ATKINSON CAREY JOE [US]) 12 August 1997 (1997-08-12) figures 5-8 -----	1-14

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

### \* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

24 September 2019

Date of mailing of the international search report

04/10/2019

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040,  
Fax: (+31-70) 340-3016

Authorized officer

Herz, Markus

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/NL2019/050429

### Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **15**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**see FURTHER INFORMATION sheet PCT/ISA/210**
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/NL2019/050429

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
W0 9838953	A1	11-09-1998	AU	6683498 A		22-09-1998
			CA	2283321 A1		11-09-1998
			US	6824528 B1		30-11-2004
			US	2005070845 A1		31-03-2005
			US	2008147016 A1		19-06-2008
			US	2010168671 A1		01-07-2010
			W0	9838953 A1		11-09-1998
-----						
US 3895741	A	22-07-1975	DE	2246054 A1		05-04-1973
			ES	407101 A1		01-10-1975
			FR	2154675 A1		11-05-1973
			GB	1398628 A		25-06-1975
			IT	980987 B		10-10-1974
			JP	S4872992 A		02-10-1973
			NL	7212990 A		30-03-1973
			SU	452936 A3		05-12-1974
			US	3895741 A		22-07-1975
			ZA	7206230 B		30-05-1973
-----						
US 5656033	A	12-08-1997	US	5505708 A		09-04-1996
			US	5656033 A		12-08-1997
-----						

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box II.1

Claims Nos.: 15

Independent method claim 15 remains to be considered a method of treatment of the human body by therapy (Rule 39.1 (iv) PCT), for which the European Patent Office, when acting as International Search Authority (ISA), does not establish an opinion: The argument, that a "delivery" is only performed "into a tubing and not into a patient" is not considered valid, since any regular use of the tubing of an "IV bag" implicitly requires a connection the tubing to a patient. This is also fully apparent from the description, see for example p. 1, li. 2-4. Since the content of an "IV bag" is normally a medicament, the intended "delivery" cannot be construed without an inherent "therapeutic effect". In this sense, it is also not considered possible to validly claim a "method of delivery" without "therapeutical effect", i.e. without violating Rule 39.1 (iv) PCT.